

**REMARKS**

At the outset, Applicant thanks Examiner Ou for his time and consideration of the present application during the telephonic interview of June 25, 2009 with the undersigned.

During the interview, the "auto-expandable element" feature was discussed relative to the written description and applied prior art. Possible amendments to the claims were discussed to clarify the "auto-expandable element", which is not taught by the applied prior art.

This application is amended in a manner to place it condition for allowance.

**Status of the Claims**

Claim 1 is amended to clarify the auto-expandable element which is described, for example, at page 7 line 3, page 9 lines 1-32, page 10 lines 20-26 and Figure 11 of the specification.

Claim 2 is amended as to form.

Claim 17 is new. Support may be found in original claims 1 and 2, at page 7 line 3, page 7, line 21 to page 8 line 2, page 9 lines 1-32, page 10, lines 20-26 and Figure 11.

Claims 1-17 are pending.

No new matter is believed to have been added.

**Claim Rejections- 35 USC §112**

Claims 1-16 were rejected under 35 USC §112, first paragraph, for not complying with the written description requirement. This rejection is respectfully traversed.

The position of the Official Action was that "an auto-expandable element (24) which presses against the internal wall of the outer envelope (2)" and " the auto-expandable element is in contact with the internal wall of the nose (14)" do not have support in the specification.

Amended claim 1 and new claim 17 do not recite these two features in this way, but, nevertheless, both the present and previously claimed features are believed to find their support in the specification as follows:

- page 9, lines 1-5:

"the distal end piece of the inner sheath (3) presses against the inner wall of the outer envelope (2) by means of an expandable element (24)".

- page 9, lines 18-25:

"More precisely, the expandable distal element (24) is maintained by the inner wall of the outer envelope (2)".

- page 9, lines 29-32:

"It causes the expandable element (24) and the inner sheath (3) to press against the inner wall of the outer envelope (2), thereby deploying the nose by pushing part the various segments (15a, 15b, 15c, and 15d)".

The expandable distal element may be auto-expandable in view of lines 2-3 on page 7.

The new recitation of expansion in the radial direction is supported by the above sections when read in view of Figures 11 and Figure 14.

Therefore, the present claims are believed to meet the written description requirement, and withdrawal of the rejection is respectfully requested.

Claims 2-5, 11-13, 15 and 16 were rejected under 35 USC §112, second paragraph, for being indefinite. This rejection is respectfully traversed.

Claim 2 was specifically rejected for the term "the expandable element (24)" , which lacked antecedent basis.

As claim 2 is amended to correct this formal matter, and withdrawal of the rejection is respectfully requested.

**Claim Rejections- 35 USC §102(b)**

Claims 1-5, 11, 15 and 16 stand rejected under 35 USC §102(b) as being anticipated by VARGAS et al. 2002/0042622 ("VARGAS"). This rejection is respectfully traversed.

The system of claim 1 includes an implant (10) with an auto-expandable element (24) which is maintained by the internal wall of the outer envelope (2) and is expandable in the radial direction. A means for translation of said implant (10) in relation to the outer envelope (2) is one such that the auto-expandable element (24) is maintained by the internal wall of the

outer envelope (2), but upon contact with the nose (14) the auto-expandable element further expands radially and opens out the segments (15a, 15b, 15c, 15d).

This structure is explain on page 9 (in light of page 7, lines 2-3) and illustrated by Figure 11 in view of Figure 14 of the present specification:

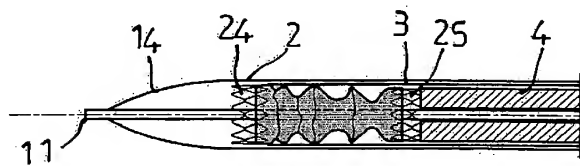


Fig.11

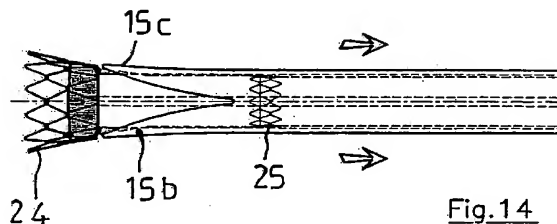


Fig.14

VARGAS, however, fails to disclose the claimed (1) an auto-expandable element and (2) the structural relationship between an expandable element, outer sleeve and nose section, such that the nose section is opened by the expandable element, as recited in independent claims 1 and 17.

Instead, VARGAS describes the following, e.g., in Figures 5 and 6:

FIG. 5

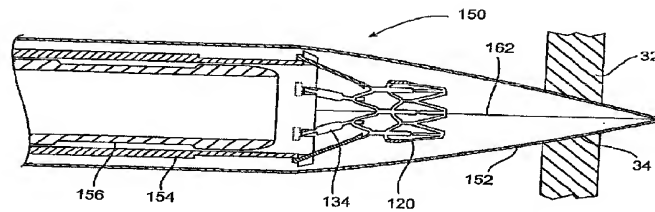
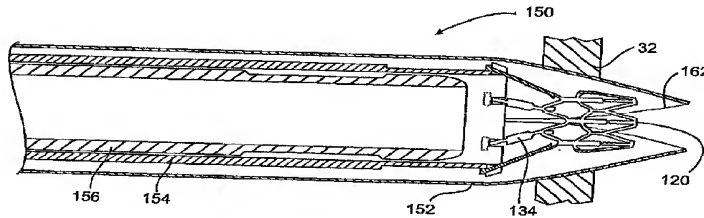


FIG. 6



The trocar (152) of VARGAS has a tapered distal end with slots for its opening. The proximal end of an anastomosis device (120) is tied to a holder tube (154).

This anastomosis device (120), however, is does not expand radially, nor is it maintained by the internal wall of the trocar (152), as seen Figure 5. Moreover, the device does not open the tapered distal end upon contact, as seen in Figure 6 .

Instead, "the advancing of the holder tube 154 causes the distal end of the trocar (152) to be forced to spread apart". (See, e.g., paragraph [0062] of VARGAS). That is, the holder tube (154) appears to be maintained the internal wall, and upon contact with the distal end, opens out the distal end, as illustrated in figure 6 above.

Moreover, it is only after the tapered distal end has been opened by the holder tube (154) that the anastomosis device (120) is expanded, i.e., by an extender tube (156). VARGAS discloses that "Once the anastomosis device 120 is in

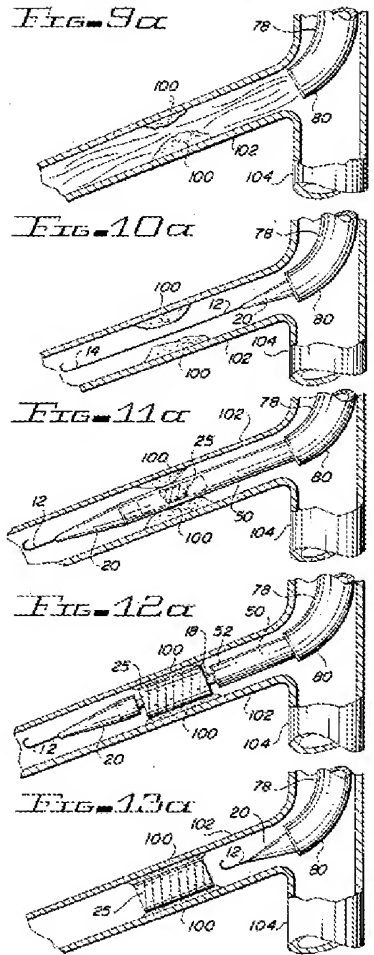
position...the inner annular flange 20 is deployed by advancing the expander tube 156 into the anastomosis device" (See, e.g., paragraph [0062])). That is, the device is not auto-expandable, otherwise upon contact with the distal end, the device, not the extender tube, would have opened out the distal end.

Therefore, VARGAS fails to disclose an auto-expandable element and the claimed structural relationship between an auto-expandable element and a nose section as described in claims 1 and 17, and withdrawal of the rejection is respectfully requested.

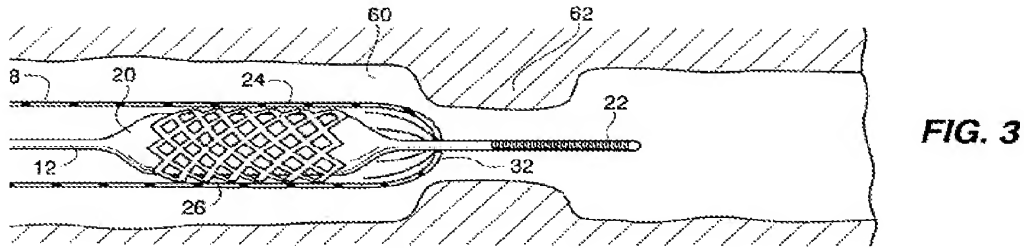
**Claim Rejections- 35 USC §103(a)**

Claims 1-16 are rejected under 35 USC §103(a) as being unpatentable over GARZA et al. US 4,665,918 ("GARZA") in view of MARTINEZ et al. US 5,593,412 ("MARTINEZ"). This rejection is respectfully traversed.

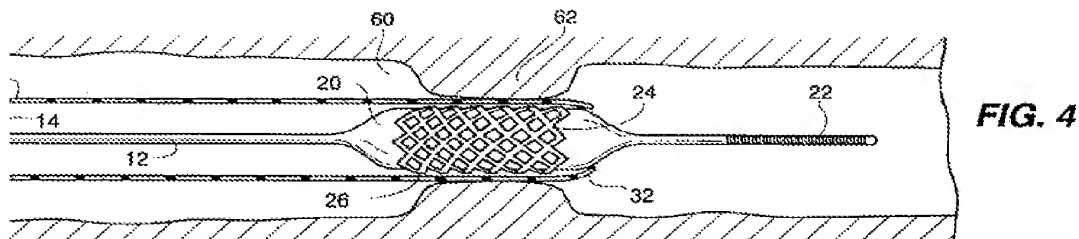
GARZA discloses a device for the introduction of an endovascular prosthesis. The prosthesis (100) is auto-expandable, and the device includes a cone section (20). However, the prosthesis is not in contact with an internal wall, nor does it open out any segment of the cone. Instead, the cone section passes through the prosthesis:



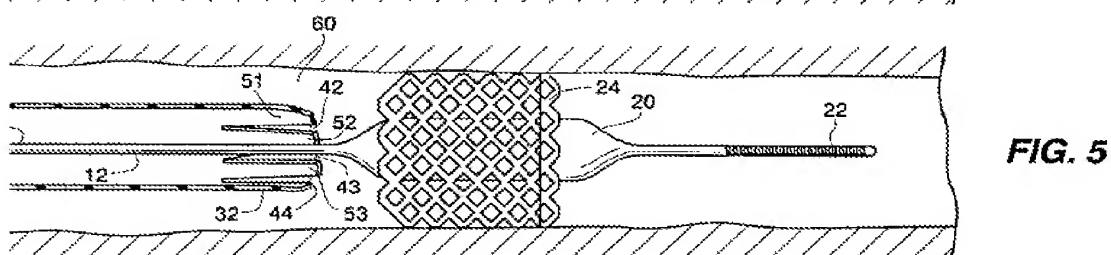
MARTINEZ discloses a stent delivery apparatus. The stent (24) is expanded by a balloon (20). This balloon is attached to a wire (22) that opens the end of an outer sheath (8), as shown below:



**FIG. 3**



**FIG. 4**



**FIG. 5**

The position of the Official Action was that it would have been obvious to include an outer envelope on GARZA with a tapered end piece with the structures suggested by MARTINEZ.

However, the combination does not teach the claimed invention, e.g., as defined in independent claims 1 and 17.

The systems of claims 1 and 17, as shown above in Figures 11 and 14, include an implant (10) with an auto-expandable element (24) which expands in the radial direction and maintained by the internal wall of an outer envelope (2). The claimed systems also include a means for translation of said implant (10) in relation to the outer envelope (2) is one such that the auto-expandable element (24) is maintained by the inner wall such that upon contact with the internal wall of the nose



(14), the auto-expandable expands further in the radial direct to open out the outer sleeve segments (15a, 15b, 15c, 15d).

The proposed combination, however, would result in the prosthesis of GARZA in contact with an internal wall of an inner envelope. The wire (12), followed by the internal nose section of GARZA, would contact the inner wall of the outer envelope to open the outer envelope, i.e., not an auto-expandable element.

Indeed, this how MARTINEZ suggests opening the outer envelope. MARTINEZ requires the wire attached to the of expandable balloon to contact and open a distal end of the outer envelope. It is only after the wire attached to the of expandable balloon passes through the open end that the auto-expandable element finally contacts the distal end.

Therefore, the proposed combination cannot render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

### Conclusion

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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